CHAD THERAPEUTICS, INC.
21622 PLUMMER STREET
CHATSWORTH, CA 91311

K010389

TEL: (818) 882-0883
FAX: (818) 882-1809
www.chadtherapeutics.com

MAR 2 3 2001

CHAD® THERAPEUTICS

SPECIAL 510(k)

510(k) SUMMARY

Chad Therapeutics, Inc.

Modified Chad Therapeutics OXYMATIC Model 401 and Model 411

February 8, 2001

Submitter Information:

Chad Therapeutics, Inc.
21622 Plummer Street
Chatsworth, CA 91311

Submitter's Name: Kevin McCulloh
Phone: (818) 882-0883

Device Name:

Proprietary names: Chad Therapeutics OXYMATIC Model 401A
Chad Therapeutics OXYMATIC Model 411A

Common Name: Oxygen conserver

Classification Name: Non-continuous ventilator

Predicate Device Equivalence:

Substantial equivalence is claimed to the Chad Therapeutics Unmodified OXYMATIC Model 401, cleared for commercial distribution per K000890 and Chad Therapeutics Unmodified OXYMATIC 411, cleared for commercial distribution per K003455.

Device Description:

The Chad Therapeutics OXYMATIC Model 401A and Model 411A is microprocessor-controlled device, which is a combination of a low-pressure regulator and an oxygen conserver, designed for use with ambulatory oxygen systems. It delivers boluses of oxygen that is equivalent to 1 to 6 liters per minute, depending on the flow rate setting.

Intended Use:

The Chad Therapeutics, Inc. OXYMATIC Model 401A and Model 411A is intended for prescription use only to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen in their home and for ambulatory use.

Comparison of Technological Characteristics:

The Model 401A and Model 411A has the same technological characteristics as the predicate devices. The hardware has been modified to have an aluminum and brass combination of materials in the regulator portion. In addition the labeling has been modified. The software portion of the device is identical to the predicate device

Summary of Testing:

Performance, mechanical, electrical, electromagnetic compatibility and environmental testing was conducted to demonstrate that the Model 401A and 411A would perform as intended.

Conclusions:

Based on the above, we concluded that the Chad Therapeutics modified OXYMATIC Model 401 (i.e., the Model 401A) and the modified OXYMATIC Model 411 (i.e., the Model 411A) are substantially equivalent to unmodified Model 401 and 411 devices and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. Kevin McCulloh
Chad Therapeutics, Inc.
21622 Plummer Street
Chatsworth, CA 91311

Re: K010389
OXYMATIC Model 401A and 411A
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II (two)
Product Code: 73 NFB

Dear Mr. McCulloh:

This letter corrects our substantially equivalent letter of March 23, 2001, regarding the OXYMATIC Model 401A and 411A. Our letter identified the product code as 73 BZD. This is in error; the correct product code is 73 NFB as indicated above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

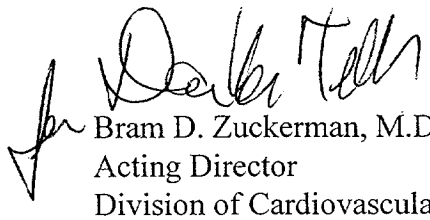
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K010389

DEVICE NAME: Modified Chad Therapeutics OXYMATIC Model 401 & 411

INDICATIONS FOR USE:

The Modified Chad Therapeutics OXYMATIC Model 401 and 411 is intended for prescription use only, to be used as part of a portable oxygen delivery system for patients that require supplemental oxygen up to 6 liters per minute, in their home and for ambulatory use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010389

Prescription Use ✓ OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1